CooperSurgical
Healthy women, babies, and families™

June 24, 2019

URGENT FIELD SAFETY NOTICE

COOPERSURGICAL TRANSWARMER® WARMING INFANT TRANSPORT MATTRESS
P/N 20421

Dear Valued CooperSurgical Customer,

CooperSurgical is issuing a Field Safety Notice for 77 lots its TRANSWARMER® Warming Infant Transport Mattress (TRANSWARMER Mattress) distributed between January 4, 2017 to May 10, 2019 (see ***Table 1*** on Page 2). The mattress is used to provide warmth during transport of infant within the hospital, or between hospitals.

CooperSurgical has updated the IFU in April 2019 to clarify that use of the TRANSWARMER Mattress with other heat producing devices, such as an incubator, is prohibited. **Such use could lead to serious health consequences**, **such as skin burns.** Please reference the updated version of the IFU included in this mailing for details on proper use of the product moving forward.

Please complete the enclosed **Acknowledgement and Receipt Form** and return it to CooperSurgical, so that we can document receipt of this letter and track customer responses to ensure patient safety.

The relevant regulatory authorities have been notified of this field safety notice. We sincerely apologize for any inconvenience caused by this safety notice. CooperSurgical is committed to high quality, safe and effective products. Please feel free to reach us at: +001.203.601.5200 ext. 3300 with any questions regarding this notice.

Sincerely,

Peter Niziolek
Product Surveillance Manager

Affected Lots		
IJ780	IJ920	IK147
IJ782	IJ924	IK162
IJ785	IJ933	IK164
IJ789	IJ946	IK171
IJ794	IJ948	IK178
IJ796	IJ957	IK184
IJ804	IJ962	IK201
IJ807	IJ973	IK214
IJ817	IJ976	IK238
IJ824	IJ982	IK252
IJ832	IJ985	IK258
IJ834	IJ999	IK265
IJ841	IK007	IK270
IJ853	IK009	IK276
IJ865	IK015	IK298
IJ874	IK028	IK318
IJ878	IK038	IK322
IJ884	IK041	IK330
IJ886	IK053	IK332
IJ892	IK060	IK339
IJ895	IK066	IK353
IJ897	IK095	IK361
IJ900	IK102	IK378
IJ902	IK107	IK384
IJ909	IK127	IK390
IJ917	IK135	

***Table 1**: Product Code: 20421, Distributed: January 4, 2017 to May 10, 2019*

Acknowledgement and Receipt Form: Response is required

Please complete this form and return it via email: recall@coopersurgical.com or fax to +**001**.**203.601.9870 ATTN: Product Surveillance.**

Customer Account #: _____ Account Name: _____

Street Address: _____ Town, State, Zip Code:_____

Contact Name: _____ Phone Number: _____

Email address: _____

I have read and understood the instructions provided in the June 24, 2019 notice.
Yes ____ No__

Any adverse events associated with this correction? Yes ___ No____

If yes, please explain:
_____

Please check the box below for confirmation:

☐ We have received the current version of the Instructions-for-Use (IFU) included in this mailing.

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at +**001**.**203.601.5200** Ext. **3300** or email us at **recall@coopersurgical.com**. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch or the respective Competent Authority's Adverse Event Reporting program either online, by regular mail or by fax.

Acknowledgement and Receipt Form: Response is required

Please complete this form and return it via email: recall@coopersurgical.com or fax to **+001.203.601.9870 ATTN: Product Surveillance.**

FOR DISTRIBUTORS ONLY:

Customer Account #: _____ Account Name: _____

Contact Name/Title: _____ Phone Number: _____

Email address: _____

Please complete the appropriate information below if applicable.

I have read and understand the safety alert instructions provided in the June 24, 2019 letter.
Yes ___ No___

I have identified and notified my customers that were shipped or may have been shipped this product by _____(Specify date and method of notification)

Or

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: _____ Date: _____

PLEASE E-MAIL COMPLETED RESPONSE FORM TO recall@coopersurgical.com OR FAX
+001.203.601.9870 ATTN: Product Surveillance